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27. <u>REMARKS</u>

The Examiner's rejection of claims 1, 4-8, and 19-26 under 35 USC § 102(b,e) as being clearly anticipated by either WO'97 or Lappe '815 is respectfully traversed. The disclosures of both these references teach the use of a cylindrical container (see reference number 11 of WO'97 and collection cup 10 of Lappe '815). As Applicant pointed out in the Amendment Under 37 CFR § 1.116, these claims have been drafted to focus attention upon the novel feature of Applicant's container having a recessed, flat front wall and a receptacle integrated with the container to locate a cassette with its substantially flat front surface near said flat front wall, with a window in the front surface facing said flat front wall, as illustrated in FIG. 1, in order to facilitate clear and easy viewing. The Examiner will see that such language appears in independent claims 1, 3 and 24; the remaining claims noted by the Examiner, with the exception of claim 16, are dependent upon one of these independent claims. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

It is submitted that claims 1, 3-8, 16 and 19-26 would not be clearly anticipated under 35 USC § 102(e) by the disclosure of U.S. Patent No. 6,342,183 to Lappe et al. (hereinafter Lappe et al.). Whereas the cup 24 disclosed in Lappe et al. does, as the Examiner points out, have a reduced rear portion 32 that is bounded by flat sides 34, the sides have undulating surfaces in order to serve as finger grips. It becomes immediately evident that the provision of such sides having raised surface features 36 would present such an "irregular configuration" that such would certainly not promote viewing into the interior of the specimen cup; instead they would very likely obscure viewing through either of the opposed, otherwise

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generally flat walls that form the finger grip portion. Moreover, as pointed out at column 5, lines 3-10, the Lappe et al. device employs a cap having a transparent top surface 42 which enables test strips mounted immediately beneath the cap to be visible therethrough; clearly, there is no intention to view anything through the finger grip surfaces. Accordingly, it is submitted that Lappe et al. does not disclose "a cassette having a substantially flat front surface slidably received within a receptacle integrated within said container and located near said flat front wall", which cassette has a window in that front surface that faces said flat front wall, as recited in claim 1. Similarly, it is submitted that there is not shown a specimen cup having a recessed flat front face and a cassette having a substantially flat front surface that is received within a receptacle integrated with said container, wherein the receptacle locates the cassette near the recessed flat front face so that a viewing area is provided close to the front surface of the cassette, as recited in claim 3. Additionally, it is submitted that Lappe et al. show neither a container having a recessed flat front wall nor an integrated receptacle located near said flat front wall, together with a cassette for insertion into said receptacle, wherein the receptacle is constructed to only receive the cassette with a window in its front surface facing said flat front wall where it will be located near said flat front wall for easy viewing, as recited in claim 24. Therefore, it is submitted that claims 1, 3 and 24, along with the claims dependent thereupon, are not fairly anticipated under § 102, and it is requested that the rejection on this basis be reconsidered and withdrawn. Discussion of rejection of claim 16 is deferred to the following section with respect to the obviousness rejection.

It is submitted that the subject matter of claims 2-3 and 11-12 and 16-18 would not be obvious in view of the disclosure of either WO'97 or Lappe et al. in combination with the

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disclosure of U.S. Patent No. 5,119,830 to Davis (hereinafter Davis). Although the primary references WO'97 and Lappe et al. do show a cup having a container lid and a cassette, they show neither a receptacle integrated with said container which receives said cassette, nor do they show a bottom floor of a container which slopes toward the bottom of said cassette, as set forth in claim 2. Both of the primary references support the cassette from the cup lid, not by the container itself, and both illustrate a container having a flat bottom surface.

It is submitted that the disclosure of Davis would not fairly suggest any modification of the specimen-testing devices shown in either of the primary references. Davis also discloses a container 12 having a <u>flat bottom</u> where a unique composite <u>lid</u> is employed. The lid has a recessed region or wall that contains test strip material and a flexible plastic cover made of stretchable Mylar or the like that is sealed to the lid upper surface to provide a test strip compartment within the lid. The objective of the Davis device is to allow a urine specimen or the like to be routinely deposited within the container 12, and after the lid is screwed in place, shipment of the sample to a laboratory can be made without any contact between the specimen and the test material in the lid compartment. To then facilitate preliminary testing, an operator opens a frangible valve in the floor of the lid compartment by pressing downward on the apex of a wedge-shaped shell 46; the valve opens as depicted in Figure 5. The operator can then tilt the cup so that the specimen will enter the lid compartment through the now open valve and thus wet the test strips contained within the compartment to cause a chemical color change to occur which is indicative of the presence of a particular substance for which the test is being conducted. Although the floor of the lid compartment does have a sloped region near the valve, the purpose of this region is not to direct liquid to a specific location, but instead, it is for just

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the opposite purpose, namely to drain liquid therefrom so that the specimen which entered the test space may easily run back into the container cavity when the analytical specimen cup 10 is returned to an upright attitude, see column 5, lines 31-32.

In view of the foregoing, it is submitted that the inclusion of such a <u>lid</u> in the structure of the primary references would <u>not</u> meet the recitations of claim 2, as discussed before with respect to the <u>sloped bottom floor</u>. Moreover, the concept of such a <u>lid compartment</u> having a <u>valve</u> and a <u>drain</u> would not fairly suggest modifying the <u>bottom surface</u> of a container used to collect a fluid specimen that would cause the specimen to be <u>channeled</u> to the bottom of a cassette that is received in a receptacle that appropriately locates it at the bottom of such a slope.

It is settled law that the combination of one reference with another is not proper unless there is some suggestion or motivation to make such a modification — which may not be only in the hindsight of Applicant's disclosure. In this respect, the decision of the CAFC in the case of *In re Fritch*, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) is particularly pertinent:

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so. ACS Hosp. Systems, Inc. v. Montefiore Hosp., 732F.2d 1572, 221 USPQ 929, 933 (Fed Cir. 1984) Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious 'modification' of the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification."

In view of the foregoing, it is submitted that the rejection of claim 2 for obviousness should be reconsidered and withdrawn.

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The rejection of claims 3 and dependent claims 11-12 was earlier discussed with respect to the primary references. For the reasons just stated above, it is submitted that Davis adds nothing to the primary references from the standpoint of showing a container having a recessed front wall to locate a viewing area adjacent to a window in a cassette. Accordingly, it is submitted that the rejection of claims 3-8 and 11-12 for obviousness should be reconsidered and withdrawn.

It is submitted that the subject matter recited in claim 16 and dependent claims 17 and 18 would not be obvious from the disclosures of either of the primary references in view of the disclosure of Davis. As stated just above, the primary references both disclose cups for collecting a specimen that have flat bottoms and a cassette that is supported solely by the lid. Davis <u>likewise</u> has such a <u>flat bottom</u> and a unique composite lid wherein an initially sealed test compartment is located. It is submitted that it should be clear that none of the references teaches the use of a cassette that is removably receivable in a receptacle in said container which cassette has a sealed window in a substantially flat front surface and an open bottom end portion which is designed to allow the fluid specimen to flow upward thereinto. Claim 16 recites that the cassette has an attached dam structure which is located so as to form a recessed pooling area in said cassette. Applicant does not employ a "one-way valve" as mentioned by the Examiner, and it is submitted that the employment in Davis of a valve (which is clearly not a one-way valve, but a valve that once manually opened stays open, as shown in Figure 5) is irrelevant to Applicant's recited dam structure that creates a pooling area. As stated hereinbefore, the sloping surface 34 in Davis is simply provided in order to drain a liquid specimen away from the test strip. Accordingly, it is submitted that, in addition to the

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arguments set forth above, any such combination of Davis with either of the primary references would be one of hindsight. It is further submitted that the recited dam structure of claim 16 is unmentioned in the rejection and clearly absent from the disclosure of Davis. Accordingly, it is submitted that the rejection of claim 16 and dependent claims 17 and 18 for obviousness should be reconsidered and withdrawn.

The rejection of claims 2 and 17 as obvious in view of the disclosure of Lappe et al. in combination with Davis is respectfully traversed. It is submitted that Lappe et al. does not disclose a cassette that is received in a receptacle integrated with a specimen in said container, which container has a bottom floor that slopes downwardly at a specific angle toward the bottom of the cassette to channel the specimen toward the cassette. Instead Lappe et al. teaches an entirely different construction, namely a cup of highly irregular molded configuration 24 and a detachable cap 26 which has a top surface 42 that is transparent to allow test strips mounted therebeneath to be visible. As shown in Figure 5B, the cap 26 includes an upper cap member 72 and a lower cap member 74; the lower cap member has descending arcuate or tubular walls 76 and 78 that extend downward into a cavity formed in the bottom of the cup. As perhaps best seen in Figure 7, a plunger pin 104 can be depressed to cause fluid to be displaced upwardly from this cavity through narrow passageways 80 so as to enter the test strip compartments 86 in the cap. It is submitted that this highly complex device, which has test strips in the cap, is not truly relevant to the subject matter recited in claim 2 discussed hereinbefore with respect to a sloped floor at the bottom of the container. The irrelevance of the disclosure of Davis in this respect was previously set forth. Therefore, it is submitted that

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the obviousness rejection of claim 2 and dependent claim 17 based on the combination of Lappe et al. and Davis simply cannot fairly stand and should be reconsidered and withdrawn.

It is submitted that claim 3 defines an invention which would not be obvious from the disclosure of either of the primary references (WO'97 or Lappe) in view of Lappe et al. As previously pointed out, both of the primary references employ cups of cylindrical configuration wherein vertically oriented cassettes, containing chemical strips that would provide an indication of a characteristic of a collected specimen, are vertically supported from a cap. Thus, neither discloses a container having a recessed flat front face and an integrated receptacle which receives said cassette and locates a substantially flat front surface of the cassette near the recessed front face so that a viewing area is close to said cassette front surface. For the reasons set forth hereinbefore, it is submitted that Lappe et al. the disclosure adds nothing to the disclosure of either of the primary references as it is directed to an entirely different type of assaying device. As previously pointed out, the relatively flat finger grip surfaces that are formed of irregular configuration would certainly not lend themselves to the creation of a "viewing area"; moreover, there is nothing there to view, as Lappe et al. locates test strip compartments adjacent transparent regions in the lid and pumps collected fluid up to the test compartment. Accordingly, it is submitted that there can be no fair combination of these references that would result in Applicant's claimed construction. Therefore, it is respectfully submitted that the rejection of claim 3 and of dependent claim 18 should be reconsidered and withdrawn.

The recitations of claim 16 have been discussed hereinbefore with respect to the provision of a cassette with an attached dam structure located so as to form a recessed pooling

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area in the cassette. As previously indicated, the disclosure of Lappe et al. which pumps a fluid specimen upward into a test compartment in a composite lid located below a transparent section is simply irrelevant. The two primary references merely suspend a flat cassette from a lid.

Accordingly, it is submitted that the rejection of claim 16 and dependent claim 18 for obviousness should be reconsidered and withdrawn.

In view of the foregoing amendments and remarks, it is believed that the claims that presently presented, i.e. claims 1-8, 11, 12, and 16-26 should be allowed and allowance thereof is respectfully requested. In the absence of any more pertinent prior art, it is submitted that this application should be found to be in condition for allowance, and issuance of a Notice of Allowance is courteously solicited.

Respectfully submitted,

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